Title: Director, Clinical Operations

Hiring Manager: Vice President, Clinical Operations

Function: Clinical Operations

Location: Waltham, MA

Position Summary:

Upstream Bio is developing innovative therapeutics in inflammation. We are a nimble company with solid financial backing that has raised $400M from high-quality investors. We are developing a monoclonal antibody targeting validated biology and are focused on our two Phase 2 studies in asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) in 2024. Our offices are in Waltham, MA. We have a hybrid working model, with Tuesdays-Thursdays in the office and Mondays and Fridays flexible to work remotely if desired.

We seek a resourceful, purpose-driven, integrative thinker for an important role overseeing our clinical trials and contributing to clinical development plan strategy across our indications. This key role will plan, oversee and drive delivery of clinical studies in a fully outsourced model. Additionally, this individual will provide guidance and shared learning throughout planning and implementation, as well as ensure clinical operational deliverables and timelines are met across the development program(s). This position will report to the Head of Clinical Operations.

The successful candidate will have a scientific background and have led programs through first in human studies and later stage development. This position requires a strong ability to synthesize scientific, clinical and business considerations into a cohesive study and program operational strategy. This individual will use outstanding cross-functional skills to achieve study and program goals and will develop a solid understanding of the clinical indications being pursued including knowledge of the patient needs, development plan, applicable regulatory guidance as well as the competitive landscape in the therapeutic space.

Excellent written and oral communication skills are required to represent the trials and program to internal and external stakeholders, as is the desire and ability to work in a small, fast-paced, and patient-focused environment. Adaptability to changing study and program needs and challenges and an innovative approach to problem solving will be important characteristics of the successful candidate.

Key Responsibilities:

- Plan, drive and oversee all aspects of large multi-center global clinical trials in compliance with GCPs, SOPs, and within designated program budgets and timelines in close collaborations with key stakeholders and Clinical Research Organizations (CROs)
- Develop and drive implementation of clinical operational strategy for successful delivery of assigned clinical studies. Lead the Study Management Team to enable the development and implementation of clinical protocols and associated plans.
- Partner with the CRO SMT lead to ensure effective risks identification & mitigation strategies as well as proactively identify & resolve issues.
- Oversee high quality implementation, execution and delivery of studies by CROs in alignment with timeline and budget plan.

- Establish an open team culture defined by transparent communication, clear goal setting, and risk-based oversight
- Provide oversight and management for all relevant CROs and vendors including contracting and clinical budgets; develop contingency plans for clinical trials.
- Ensure compliance with internal policies and procedures, GCPs, and applicable regulations; ensure inspection readiness
- Contribute to CRO/vendors identification, qualification and selection processes as applicable.
- Meaningfully contribute to the planning and implementation of clinical development programs including scenario planning, timeline forecasting, program level feasibility assessments, estimation of resources and budget, and development of operational strategies.

Qualifications

- Bachelor's Degree or international equivalent required; Life Sciences preferred. Advanced degree highly desirable.
- 10+ years of relevant clinical development and operations experience, in clinical operations leadership roles, leading global clinical studies/programs, with track records of initiating and delivering large Phase 2 and/or Phase 3 trials.
- Experience overseeing respiratory clinical trials preferred.

Skills, Knowledge & Abilities

- Strong leadership skills driving large cross functional teams.
- Deep knowledge of global regulatory and compliance requirements for clinical research, local country requirements and ICH GCP, including experience with global regulatory inspections.
- Excellent critical and strategic thinking, with strong ability to understand the big picture as well as the important details that may impact the big picture.
- Global clinical operations & development experience across therapeutic areas with demonstrated ability to rapidly learn new indications
- Excellent communicator and influencer, able to persuasively convey both ideas and data, verbally and in writing.